ISO 9001 Quality Management System - Lead Auditor IRCA Certification Training

40 hours

This course teaches the principles and practices of effective quality management system audits in accordance with ISO 9001 and ISO 19011, “Guidelines for auditing management systems”.

Experienced MassMEP tutors will guide trainees through the entire audit process, from initiating the audit to conducting audit follow-up.

Trainees will gain auditing skills developed through a balance of:

- formal classroom tutorials
- practical role-playing
- group workshops, and
- open forum discussions

Course Benefits

Successful completion of this IRCA certified training course by passing the IRCA examination and skills assessment, will demonstrate knowledge and basic skills to undertake and lead a management systems audit.

Course Structure

A combination of tutorials, exercises and role play, including the following topics:
Explain the purpose and business benefits of:

- a Quality Management System;
- management system audit;
- third-party certification.
- Explain the role of an auditor to
    - plan,
    - conduct
    - report
    - follow up a Quality MS audit in accordance with ISO 19011 (and ISO 17021 where appropriate)

Have the skills to:

- Plan
- Conduct
- Report
- And follow up an audit of a Quality Management System to establish conformity with ISO 9001, ISO 19011

Audience

- Quality Management System Leaders
- Managers, Supervisors, Management Representatives
- Quality Management System Specialists
- Auditors, Project Leaders, Implementation Leaders
- Internal auditors
- audit team members

Pre-requisites:

It is strongly recommended that the participants have a basic knowledge of the requirements of ISO 9001:2015, and have performed QMS audits before they attend this course. An attendee should consider attending the ISO 9001 QMS Foundation & Internal Auditor course and completing some audits before attending.

IRCA Certified Course (***Course Reference No. A17952***)

This course is certified by the International Register of Certificated Auditors (IRCA) and meets the training requirements for IRCA QMS auditor certification.

LEAD AUDITOR QUALITY MANAGEMENT SYSTEM (QMS)

CONTENT

- Course Objective
- Prior Knowledge and Skills
- Content, Learning Objective and Duration
- Accelerated Learning Methodology
- Installations, Equipment and Materials
- Conditions to Provide the Exam
- Documents and Records
- Selection of Participants in Audit Groups
- Grading Process of Continuous Evaluation
- Course Content and Activities

Day 01 - Detailed Schedule

- Pre-check of the Infrastructure and H&S Welcome and Introduction
- Quality Management Exercises
- Fundamentals of ISO 9000 and Requirements of ISO 9001 Audit Cases

Day 02 –Detailed Schedule

- Certification Process Exercises
- Audit as a Tool for Assessment Exercises

Day 03 –Detailed Schedule

- The Audit Process Exercises

Day 04 –Detailed Schedule

- Role Play Audit Model Exam

Day 05 –Detailed Schedule

- Role Play Audit Conclusion
- Evaluation by Participant Final Exam

Objective

The objective of this course is to provide participants with the knowledge and the ability to lead audits of first, second and third part of Quality Management Systems that meet the criteria of ISO 9001 according to ISO 17021 and ISO 19011, as applicable.

Knowledge should be appropriate to describe the purpose of a Quality Management System, of standards for quality management systems, the audit of management system, a third part certification and the importance of internal audit.

The skill should be appropriate to plan, conduct, report and monitor the audit of a Quality Management System to verify compliance with ISO 9001. Criteria for audit shall be in accordance with ISO 17021 or with ISO 19011, as applicable.

The Lead Auditor Course for the Quality Management System is the Exam required by GLOBAL as part of the Personnel Certification process in this Qualification.

The Exam Program meets the GLOBAL Certification Program PC01 - Auditor, in accordance with the ISO 17024 standard, and meets the requirements for CQI and IRCA registered courses.

The Course Program indicates content, learning objectives, duration and specific aspects to the application of the Exam, including audit simulation. Full list of documents, records, equipment and materials applicable to the Exam are clearly indicated, as well as issues relating to the facilities required to the implementation of the Exam

Prior Knowledge and Skills

The instructor must consider that the Participants of the Lead Auditor Course for Quality Management System must demonstrate prior knowledge on the following items:

- Management system
  - PDCA Cycle
  - Core elements of a management system and the interrelationship between top management, responsibility, policy, objectives, planning, implementation, measurement, review and continuous improvement.
- Quality Management
  - The Seven Quality Management Principles, as in ISO 9000:2015
  - Relationship between Quality Management and Customer Satisfaction

- ISO 9001:2015
  - Requirements of ISO 9001
  - Commonly used Terms and Definitions of Quality Management as in ISO 9000:2015

It is advisable that the participant has prior experience in auditing activities.

Content, Learning Objectives and Duration

The Exam is designed to confirm that the participants developed the knowledge and skills necessary to act as Lead Auditor for Quality Management System. The instructor has the objective to observe the participants and to assess individually each participant on the effective achievement of this goal.

The course is presented in 40 hours of classroom. The content is divided into five Modules with eleven Sections each of them with specific objectives and compatible duration, as indicated in the Table 1 below.

TABLE 1 - CONTENT, OBJECTIVE, DURATION OF COURSE

	Content	**Learning Objective**	**Instruction Time**	**Participant Time**
Module 1	Section 1.0 Introduction	• Inform about GLOBAL, IRCA and registration of auditors. The standard ISO 17024. • Inform the objectives of the course and the evaluation of participants. • Inform about the premises and administrative	30 minutes	
Module 2	Section 2.1 Management Quality	• Describe the purpose of a system to manage quality. • Explain the benefits of the quality management system for the business. • Describe the quality management system 60 min standards.	60 minutes	
Module 2	Section 2.2 Fundamentals and Vocabulary of ISO 9001:2015 and requirements of ISO 9001:2015	• Understand the Fundamentals and Vocabulary of ISO 9000:2015 and describe the standard ISO 9001:2015 • Describe the criteria applicable to a management system complying with ISO 9001:2015	90 Minutes	

Module 2	Section 2.2 Fundamentals and Vocabulary of ISO 9001:2015 and requirements of ISO 9001:2015	• Describe the processes involved in establishing, • implementing, operating, monitoring, reviewing, • maintaining and improving the QMS. • Understand the requirements of the QMS and the documented information required.		
Module 2	Section 2.3 Audit Cases	• Case study of audit situations related to ISO 9001:2015		300 Minutes
Module 3	Section 3.1 Certification Process	• Describe the purpose and steps of the third-party accredited certification • Explain the benefits of third-party accredited certification of quality management system to the organization and stakeholders.	60 Minutes	60 Minutes
Module 4	Section 4.1 Audit as a tool for evaluation	• Describe the purpose of the audit of management system. • Explain the role of each audit group member in the quality management system audit according to ISO 17021 and ISO 19011	60 Minutes	300 Minutes
	Section 4.2 The Audit Process	• 1)Plan, conduct, report and follow up of quality management audit performed to verify conformance with ISO 9001 according to ISO 17021 and ISO 19011. • Confirm proper implementation, operation, monitoring, reviewing, maintenance and improving of the QMS and the role of the auditor in assessing the ability of the organization to meet customer, statutory and regulatory requirements to product and the requirements of the own organization.	60 Minutes	420 Minutes

Module 4	Section 4.3 Simulated Audit	• Perform the Simulated Audit playing different roles in the audit team		480 Minutes